Neurosurgical Specialties
of NEPA, Inc.

David J. Sedor, M.D.
BOARD CERTIFIED NEUROSURGEON

150 Mundy Street
Medical Arts Center IV
Wilkes-Barre, PA 18702

October 2, 2000

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

To Whom It May Concern:

As a Neurosurgeon with extensive experience with totally implantable spinal cord stimulators (SES), I am in strong opposition to FDA's intention to reclassify this device from Class III to Class II.

I feel that such a move would eliminate many of the normal checks and balances in the evolution of these devices.

I would also like to point out that in 1995 the FDA classified these devices as "potentially high risk." The fact that the agency is now planning to reclassify these agents is of course a cause for great concern. I am very concerned with the potential change in quality of such devices and feel that it is important to continue to maintain such devices in the Class-III category.

Thank you for your careful consideration of my comments. Please contact me at 570-823-3300 if I can give you any additional help or information.

Sincerely,

David J. Sedor, M.D.
Diplomate, American Board of Neurological Surgery

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00P-0788

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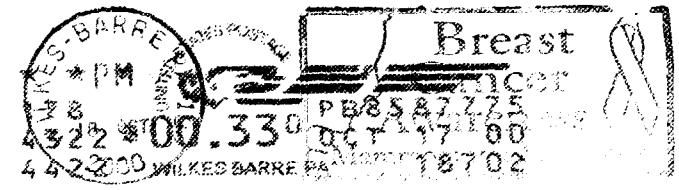

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